K031564 1 of 2

OCT - 7 2003

Medical Scientific, Inc.
125 John Hancock Rd.
Taunton, Ma. 02780
Tel: 508-880-7313
Fax: 508-880-7347

510K Summary of Safety and Effectiveness
May 12, 2003
CSS
A Modification to the
MSI Bipolar Sheath

1. Sponsor Name

   Medical Scientific, Inc.
   125 John Hancock Rd.
   Taunton, Ma. 02780

2. Device Name

   Proprietary Name: CSS
   Common Name: Coagulation Device
   Classification Name: Electrosurgical cutting and coagulation device and accessories

3. Identification of Legally Marketed Device

   MSI Bipolar Sheath, K011202
   Stryker Serfac K991960

4. Device Description

   The CSS is an accessory device that is intended to be used in conjunction with currently marketed automated debrider systems and ESU's the same as the current MSI Bipolar Sheath. The CSS is designed to fit directly over various sizes of straight automated debrider system blades. The CSS will be available in a variety of diameters and in lengths. When the CSS is inserted over one of the debrider blades, the device may be used to cauterize tissue. The CSS can be utilized to provide spot coagulation or to coagulate tissue while the debrider blade is in operation.

5. Intended Use

   The CSS is intended to be used in conjunction with the powered debrider cutter systems to cut and coagulate soft tissue during various arthroscopic surgical procedures.

6. Comparison of Technological Characteristics

The CSS is substantially equivalent in design, materials, construction and intended use as those of the predicates identified above. Since the CSS is the same in intended use and technological characteristics as the predicate devices, the CSS does not raise any new safety and efficacy concerns when compared to these similar legally marketed devices. The differences in power have been substantiated through applicable performance testing.

7. Performance Testing

Bench testing was conducted to determine device functionality and conformance to design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 7 2003

Mr. Paul Nardella
President
Medical Scientific, Inc.
125 John Hancock Road
Taunton, Massachusetts 02780

Re: K031564
Trade/Device Name: CSS
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 8, 2003
Received: September 12, 2003

Dear Mr. Nardella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031564

Device Name: CSS

Indications For Use:

The CSS is intended to be used in conjunction with the powered debrider cutter systems to cut and coagulate soft tissue during arthroscopic surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031564